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APPLICATION NO.		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/743,750		01/16/2001	Ichiro Azuma	0020-4802P	7730	
2292	7590	06/20/2005	. .	EXAMINER		
BIRCH ST PO BOX 74		r KOLASCH &	FORD, VANESSA L			
		VA 22040-0747		ART UNIT	PAPER NUMBER	
				1645		
				DATE MAILED: 06/20/2005		

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)		
09/743,750	AZUMA ET AL.		
Examiner	Art Unit		
Vanessa L. Ford	1645		

Before the Filing of an Appeal Brief	Examiner	Art Unit						
	Vanessa L. Ford	1645						
The MAILING DATE of this communication appears on the cover sheet with the correspondence address								
THE REPLY FILED 06 April 2005 FAILS TO PLACE THIS APP	PLICATION IN CONDITION FOR A	LLOWANCE.						
 The reply was filed after a final rejection, but prior to filing applicant must timely file one of the following replies: (1) application in condition for allowance; (2) a Notice of Application in condition for allowance; (2) a Notice of Application in condition for allowance; (2) a Notice of Application in condition for allowance; (2) a Notice of Application in condition for allowance; (3) a Notice of Application in condition for allowance; (2) a Notice of Application in condition for allowance; (3) a Notice of Application in condition for allowance; (3) a Notice of Application in condition for allowance; (3) a Notice of Application in condition for allowance; (3) a Notice of Application in condition for allowance; (3) a Notice of Application in condition for allowance; (3) a Notice of Application in condition for allowance; (3) a Notice of Application in condition for allowance; (3) a Notice of Application in condition for allowance; (3) a Notice of Application in compliance; (4) a Notice of Application in compliance; (5) a Notice of Application in compliance; (6) a Notice of Application in compliance; (6) a Notice of Application in compliance; (7) a Notice of Application in compliance; (8) a Notice of Application in compliance; (8) a Notice of Application in compliance; (9) a Notice of Application in compliance; (1) a No	g a Notice of Appeal. To avoid abain an amendment, affidavit, or other beal (with appeal fee) in compliance with 37 CFR 1.114. The reply mustate of the final rejection. Isory Action, or (2) the date set forth in the an SIX MONTHS from the mailing date of the ONLY CHECK BOX (b) WHEN THE FI	ndonment of this applevidence, which place with 37 CFR 41.31; st be filed within one e final rejection, whichever the final rejection.	or (3) a of the following er is later. In no					
Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL								
 The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on <u>06 April 2005</u>. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). AMENDMENTS								
3. The proposed amendment(s) filed after a final rejection, (a) They raise new issues that would require further co (b) They raise the issue of new matter (see NOTE belo (c) They are not deemed to place the application in be appeal; and/or	nsideration and/or search (see NO w);	TE below);						
(d) They present additional claims without canceling a NOTE: (See 37 CFR 1.116 and 41.33(a)).			VDTOL 224)					
4. The amendments are not in compliance with 37 CFR 1.1		ompliant Amendment	(PTOL-324).					
 5. Applicant's reply has overcome the following rejection(s 6. Newly proposed or amended claim(s) would be a the non-allowable claim(s). 	llowable if submitted in a separate							
7. For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is protected. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: <i>None</i> .	☐ will not be entered, or b) ☐ wided below or appended.	ill be entered and an	explanation of					
Claim(s) objected to: <u>None</u> . Claim(s) rejected: <u>21-26</u> . Claim(s) withdrawn from consideration: <u>1-3,5-8,10,11 an</u>	<u>d 13-20</u> .		·					
AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, b	ut before or on the date of filing a N	Notice of Appeal will r	not be entered					
because applicant failed to provide a showing of good ar and was not earlier presented. See 37 CFR 1.116(e).	nd sufficient reasons why the affida	vit or other evidence	is necessary					
9. The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to a showing a good and sufficient reasons why it is necessar	overcome <u>all</u> rejections under appe ry and was not earlier presented. S	eal and/or appellant fa See 37 CFR 41.33(d)((1).					
10. The affidavit or other evidence is entered. An explanation REQUEST FOR RECONSIDERATION/OTHER	on of the status of the claims after o	entry is below or attac	ched.					
11. The request for reconsideration has been considered by see Advisory attachment.			ance decause:					
 12. ☐ Note the attached Information Disclosure Statement(s). 13. ☐ Other: Advisory attachment. 	(F10/30/00 01 F10-1449) Paper	140(5)						

Continuation of 5. Applicant's reply has overcome the following rejection(s): rejection of claims 21-25 under 112, 2nd paragraph, page 14, paragraphs 9 and 10 of the Final Office action.

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Advisory Attachment

- 1. This Office Action is responsive to Applicant's amendment and response filed April 6, 2005. Claim 21 has been amended. Claims 4, 9 and 12 have been cancelled. Claims 1-3, 5-8, 10-11 and 13-20 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. It should be noted that no second submission declaration by Dr. Nomura filed under 37 CFR 1.132 has been received. It should be noted that Zbar et al (*Journal of National Cancer Institute, Vol. 48, No.3, p. 831-835*), submitted by Applicant is acknowledged.
- 2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

- 3. In view of Applicant's amendment the following rejections are withdrawn.
 - a) Rejection of claims 21-25 under 35 U.S.C. 112, second paragraph page 14, paragraph 9.
 - b) Rejection of claims 21-25 under 35 U.S.C. 112, second paragraph page 14, paragraph 10.

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Rejections Maintained

4. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and 26 for the reasons set forth on pages 3-5 paragraph 5 of the previous Office Action.

The rejection was on the grounds that Yamamura et al teach compositions comprising Nocardia ruba cell wall skeleton, squalene, a suspending agent and dispersing agent (see the Abstract). Yamamura et al teach that cell wall skeleton used in the invention can be derived from Mycobacterium bovis (column 2, lines 15-21). Yamamura et al teach the composition was prepared using suspending agents such as Tween and Span (surfactants) (column 2, lines 54-68). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Yamamura et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See <u>In re Best</u>, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and <u>In re Fitzgerald et al.</u>, 205 USPQ 594.

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Applicant urges the Examiner misunderstands the invention described in Yamamura et al. Applicant urges that Yamamura et al describe ethanol or acetone as organic solvents used to wash the CWS that has been prepared from culture. Applicant urges that Yamamura et al do not describe or suggest any preparation method wherein an organic solvent is used in the preparation of a mixture of BCG-CWS and an oil. Applicant refers to the Zbar et al, 1975 reference to support their position. Applicant refers to the declaration submitted by Dr. Nourma (second declaration) to support their position.

Applicant's arguments filed April 6, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claimed invention is not directed to a process of producing an oil-in-water emulsion. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. Yamamura et al teach compositions comprising cell wall skeleton that are derived from *Mycobacterium*, squalene, a suspending agent and dispersing agent. Claim limitations such as particle diameter of droplets would be inherent in the teachings of the prior art. Applicant is arguing limitations that are not in the claims with their assertions that the product of Zbar et al (a composition comprising BCG cell wall and oil droplets) would not be effective in drug efficacy, that the product of Zbar et al do not have the same level of purity as the claimed invention and that the product of Zbar et al would not be effective as an anti-tumor agent. There are no limitations in the claims regarding "drug efficacy" or "level of purity". To address Applicant's comments regarding the product of

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Zbar et al as not being effective as an anti-tumor agent, it appears that this argument is directed to intended use of the product and not the product itself. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

To address Applicant's comments regarding the Declaration of Dr. Nomura, no second declaration has been received. There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

5. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and 26 for the reasons set forth on pages 6-7 paragraph 8 of the previous Office Action.

The rejection was on the grounds that Cantrell teaches vaccines comprising cell wall skeleton which is obtained from microorganisms including *Nocardia rubra* and *Mycobacterium bovis* (column 4, lines 54-68) and squalene (oil). Cantrell teaches that the oil is combined with a detergent (i.e. Tween or Arlacel) (surfactant) (column 7, lines 27-35). Cantrell teaches the formation of oil droplet emulsions (column 7, lines 35-40 and column 10). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μ m or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μ m" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a

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particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Cantrell anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See <u>In re Best</u>, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and <u>In re Fitzgerald et al.</u>, 205 USPQ 594.

Applicant urges that the prior art reference does not describe or suggest any preparation method wherein an organic solvent is used in the preparation of a mixture of BCG-CWS and an oil. Applicant refers to the Zbar et al, 1975, in which Applicant asserts that it. Applicant refers to the declaration submitted by Dr. Nourma to support their position.

Applicant's arguments filed April 6, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claimed invention is not directed to a process of producing an oil-in-water emulsion. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. Yamamura et al teach compositions comprising derived from cell wall skeleton, squalene, a suspending agent and dispersing agents. Claim limitations such as particle

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diameter of droplets would be inherent in the teachings of the prior art. Applicant is arguing limitations that are not in the claims with their assertions that the product of Zbar et al (a composition comprising BCG cell wall and oil droplets) would not be effective in drug efficacy, that the product of Zbar et al do not have the same level of purity as the claimed invention and that the product of Zbar et al would not be effective as an anti-tumor agent. There are no limitations in the claims regarding "drug efficacy" or "level of purity". To address Applicant's comments regarding the product of Zbar et al as not being effective as an anti-tumor agent, it appears that this argument is directed to intended use of the product and not the product itself. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967). To address Applicant's comments regarding the Declaration of Dr. Nomura, no second declaration has been received. There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion. There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

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6. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and 26 for the reasons set forth on pages 6-7 paragraph 8 of the previous Office Action.

The rejection was on the grounds that Yarkoni et al teach oil-in-water emulsions comprising Mycobacterium bovis BCG cell walls, squalane and Tween (surfactant) (page 881). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm" would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe. 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Yarkoni et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See <u>In re Best</u>, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and <u>In re Fitzgerald et al.</u>, 205 USPQ 594

Applicant urges that the prior art reference does not describe or suggest any preparation method wherein an organic solvent is used in the preparation of a mixture of BCG-CWS and an oil. Applicant refers to the Zbar et al, 1975 reference to support their position. Applicant refers to the declaration submitted by Dr. Nourma to support their position.

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Applicant's arguments filed April 6, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claimed invention is not directed to a process of producing an oil-in-water emulsion. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil.

Yarkoni et al teach oil-in-water emulsions comprising Mycobacterium bovis BCG cell walls, squalane and Tween (surfactant). Applicant is arguing limitations that are not in the claims with their assertions that the product of Zbar et al (a composition comprising BCG cell wall and oil droplets) would not be effective in drug efficacy, that the product of Zbar et al do not have the same level of purity as the claimed invention and that the product of Zbar et al would not be effective as an anti-tumor agent. There are no limitations in the claims regarding "drug efficacy" or "level of purity". To address Applicant's comments regarding the product of Zbar et al as not being effective as an anti-tumor agent, it appears that this argument is directed to intended use of the product and not the product itself. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967). To address Applicant's comments regarding the Declaration of Dr. Nomura, no second declaration has been received. There is nothing

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on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion. There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion.

7. The rejection under 35 U.S.C. 102(b) is maintained for claims 21, 23-25 and 26 for the reasons set forth on pages 4-6 paragraph 7 of the previous Office Action.

The rejection was on the grounds that Van Nest et al teach compositions (oil-inwater emulsions) comprising bacterial components, oils, emulsifying agents (dispersion-aiding solvent), detergents (surfactants) in the form of oil droplets (see the Abstract). Van Nest et al teach that the composition of the invention comprise cell wall skeleton from Mycobacteria (column 9, lines 8-15). Van Nest et al teach that the oils used in the composition include squalene (column 4, lines 45-48). Van Nest et al teach that emulsifying agents include in the composition include ethanol (column 10, lines 58-63). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100 μm or less is homogeneously dispersed" and "wherein the particle diameter is about 25 μm " would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Van Nest et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material

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structural and functional characteristics of the claimed emulsion). See <u>In re Best</u>, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and <u>In re Fitzgerald et al.</u>, 205 USPQ 594.

Applicant urges that the prior art reference does not describe or suggest any preparation method wherein an organic solvent is used in the preparation of a mixture of BCG-CWS and an oil. Applicant refers to the Zbar et al, 1975 reference to support their position. Applicant refers to the declaration submitted by Dr. Nourma to support their position.

Applicant's arguments filed April 6, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is urging process limitations in a product claim. The claimed invention is not directed to a process of producing an oil-in-water emulsion. The claims are directed to an oil-in-water emulsion (a product) which comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. Van Nest et al teach compositions (oil-in-water emulsions) comprising bacterial components, oils, emulsifying agents (dispersion-aiding solvent), detergents (surfactants) in the form of oil droplets. Applicant is arguing limitations that are not in the claims with their assertions that the product of Zbar et al (a composition comprising BCG cell wall and oil droplets) would not be effective in drug efficacy, that the product of Zbar et al do not have the same level of purity as the claimed invention and that the product of Zbar et al would not be effective as an anti-tumor agent. There are no limitations in the claims regarding "drug efficacy" or "level of purity". To address Applicant's comments regarding the product of Zbar et al as not being effective as an anti-tumor agent, it appears that this argument is directed to intended use of the product

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and not the product itself. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967). To address Applicant's comments regarding the Declaration of Dr. Nomura, no second declaration has been received. There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as the claimed oil-in-water emulsion. There is nothing on the record to show that the oil-in-water emulsion of the prior art is not the same as

Status of Claims

8. No claims allowed.

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Conclusion

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov./. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford

Biotechnology Patent Examiner

June 10, 2005

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